DETAILED ACTION

Claims 2-15 have been canceled. Claims 16-18 have been added. Claims 1 and 16-18 are pending and under consideration.

The title will have to be changed to more closely reflect the claimed invention. The title –Transgenic mice expressing baculovirus soluble gp64 and methods of using such mice to make antibodies— would be appropriate.

Claim Rejections - 35 USC § 101

The rejection of the claims under 35 U.S.C. 101 because the claimed invention lacks patentable utility has been withdrawn.

Claim Rejections - 35 USC § 112

Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing an antibody against a membrane protein comprising:

(a) immunizing the transgenic mouse of claim 1 with a baculoviral particle, wherein the baculoviral particle comprises a nucleic acid sequence encoding a membrane protein, and wherein the membrane protein is displayed on the surface of the baculoviral particle;

(b) recovering an antibody from the transgenic mouse, wherein the antibody recognizes the membrane protein, does not reasonably provide enablement for immunizing the transgenic mouse with an immunogen comprising i) a baculoviral particle or portion thereof, and ii) a target antigen as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make and/or use the invention commensurate in scope with these claims.

Support for "membrane protein" is in original claim 14. Support for displaying the membrane protein on the surface of the baculoviral particle can be found on pg 10, lines 12-15 and 21-24.

Claim 1 is directed toward a transgenic mouse whose genome comprises a nucleic acid sequence encoding baculovirus gp64, wherein the gp64 is soluble and lacks a tansmembrane region and wherein the mouse is fertile. Claim 16 is drawn to a method making antibodies by i) immunizing the transgenic mouse of claim 1 with an immunogen comprising baculovirus particle or portion thereof and a target antigen, and ii) obtaining an antibody against the target antigen.

The specification teaches making transgenic mice expressing the extracellular, soluble region of baculovirus gp64 (SEQ ID NO: 3) (pg 16, lines 18-20; pg 17, lines 14-33). The specification states mice were immunized with a budding baculovirus (pepT1-AcMNPV (pepT1-VB)) (sentence bridging pg 19-20), and then states mice were given 1 mg/animal (pg 20, lines 2-7). The specification states mice expressing soluble gp64 induced tolerance (pg 20, lines 17-19; Fig. 3). However, the specification does not clearly set forth the structure of what was administered to the mice. Baculovirus is not administered at 1 mg/animal, for example (pg 20, line 7); viral doses are measured in particle numbers or infectious units, not milligrams. The structure of pepT1-AcMNPV used to immunize the mice is wholly unclear. Furthermore, applicants do not teach

obtaining antibodies against pepT1 or provide adequate guidance that antibodies against pepT1 actually occur.

Since the time of filing, Saitoh (J. Immunological Methods, 2007, Vol. 332, pg 104-117) taught sgp64 transgenic mice were immunized with PepT1 expressed on the surface of baculoviral particles and obtained antibodies against pepT1. Saitoh is considered post-filing evidence for obtaining antibodies against pepT1.

The specification fails to enable those of skill in the art at the time of filing to immunize the transgenic mouse with any "immunogen" comprising i) a baculovirus or portion thereof and ii) a target antigen as broadly claimed. The specification fails to teach how to introduce the target antigen in context of a portion of a baculovirus. The specification fails to teach how to immunize without the target antigen being expressed by the baculovirus particles. The specification fails to teach how to introduce the target antigen expressed inside the baculoviral particle and not with the envelope proteins on the surface of the particle. If the target antigen is not expressed in context of baculovirus, then using the transgenic of claim 1 is moot because the method can be performed with a wild-type mouse. If the target antigen is expressed inside the baculoviral particle but not displayed on the surface, the antigen would not induce an antibody response because the humoral immune system (for antibody production) would not have access to a target antigen. The specification fails to teach how to immunize with a baculoviral particle expressing a non-membrane protein. Thus, it would have required those of skill undue experimentation to determine how to obtain

antibodies against the target antigen. Given the lack of teachings in the specification taken with the post-filing evidence, the claims should be limited to

While the membrane protein encompasses gp64 baculovirus antigen, which is not a useful target antigen in the method claimed because the specification states the mice are tolerized to gp64, this is considered a non-operative embodiment.

Double Patenting

Claims 16-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22 and 23 of copending Application No. 10/516603. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both require making antibodies against a target antigen using a transgenic mouse expressing gp64 that is immunotolerant to gp64 using a “baculovirus or portion thereof” ('690) or a "budding virus or portion thereof" ('603). The species of “baculovirus or portion thereof” ('690) is an obvious variant of a "budding virus or portion thereof" ('603). The “pepT1” expressed by the budding virus or portion thereof in '603 is an obvious variant of the “target antigen” expressed by the baculovirus of ‘690. Otherwise, the claims have different wording that does not patentably distinct the claims of ‘603 from those of ‘690. Accordingly, the claims are not patentably distinct because the different species/genus within the claims are obvious variants and could have been claimed in either application. Issuing each application separate patent terms would unjustly extend the patent term for one invention. The claims in each application are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

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Patent Examiner